

After two consecutive rounds of "invasion" of the COVID-19 epidemic in Wuhan and Beijing, the COVID-19 epidemic in China has basically been effectively controlled. However, the global pandemic of COVID-19, which continues to refresh human history outside the country, reminds us all the time that the threat caused by COVID-19 has not really been eliminated. In the post-epidemic era, how to take off the mask and return to a normal life has become a mist of doubt in the public mind.

Many scholars, including the top infectious disease expert Anthony Fauci in the United States, have pointed out that we will not be able to completely stop the epidemic without a vaccine. And based on the current understanding of the COVID-19, many domestic experts and scholars also believe that if the first half of the "blocking war" of this epidemic is mainly based on prevention and treatment, then the second half will mainly rely on the advent of vaccines. Fortunately, China, which was the first to emerge from the storm of the COVID-19, is currently in the world's first leading position in the research and development of new COVID-19 vaccines.

Recently, Yang Xiaoming, chairman of Sinopharm group China Biotechnology Co., Ltd., which is mainly responsible for the research and development of China's COVID-19 inactivated vaccine, said in an exclusive interview with a reporter from Global Times-Global.com that it is optimistic that the domestically produced COVID-19 inactivated vaccine will be launched at the end of this year or early next year at the earliest.



The COVID-19 vaccine has become a "killer" weapon in the fight to defeat the epidemic

According to statistics from Johns Hopkins University in the United States, as of July 16, 2020, more than 13.5 million people worldwide have been diagnosed with COVID-19, and the death toll has reached more than 580,000 people, of which the COVID-19 in the United States was confirmed there were more than 3.49 million people and more than 130,000 deaths. The Daily Epidemic Report issued by the WHO on July 12 showed that 230,370 new cases of COVID-19 were confirmed in the world within 24 hours, a record high in a single day.

The global COVID-19 epidemic, which continues to set historical records, indicates that mankind can no longer expect the epidemic to disappear naturally. It is very likely that the situation similar to the sudden disappearance of the SARS epidemic in 2003 will no longer occur. The continuous deterioration of the global new COVID-19 epidemic also means that the concept of "herd immunity" put forward by some western countries is completely bankrupt, and that vaccines become the "ultimate weapon" to end the COVID-19 epidemic has become the consensus of countries around the world.

Regarding the special mission of vaccines in the "war against the COVID-19 epidemic", Yang Xiaoming, chief scientist of the vaccine project of the Ministry of Science and Technology "863 Program" and chairman of China Biotechnology Co., Ltd., said that the effective control of China's COVID-19 epidemic has benefited from the measures taken by the Chinese government. Strict quarantine measures have been used to block it, but vaccines are the most powerful weapon to end the epidemic, and the key to normal operations across the country and even the world. Only by successfully developing safe, effective, and sufficient vaccines and supplying and using them as quickly as possible is the fundamental strategy for mankind to ultimately defeat the new COVID-19.

"From the perspective of human development history, it was the emergence and widespread use of vaccines that really ended smallpox, eliminated polio, and controlled measles, diphtheria, whooping cough, tetanus and other diseases. Vaccines has made a huge contribution and can help humans reduce the harm of infectious diseases. We believe that the COVID-19 vaccine is the 'killer' for decisively fighting the epidemic." Yang Xiaoming said.



Simultaneous testing and mass production, striving to meet global vaccination demand

According to data released by the World Health Organization, there are currently more than 100 new COVID-19 vaccine projects in the world at the same time. Among them, vaccine projects in China, the United States and the United Kingdom have all entered the clinical trial stage. In the first half of 2020, China will have at least 6 teams of the COVID-19 vaccine, including the scientific research leadership team under the command of Sinopharm Group Yang Xiaoming, and the Chen Wei team of the Academy of Military Medicine of the Academy of Military Sciences. China has entered the clinical trial stage and has become a global research and development. The country with the most significant results of the new COVID-19 vaccine, are in the United States, namely Moderna's mRNA vaccine, Pfizer's mRNA vaccine, and INOVIO's DNA vector vaccine; in addition, the adenovirus vector vaccine developed by the University of Oxford in the United Kingdom has also been developed and entered the clinical trial stage.

Among the six Chinese vaccines which entering the clinical trial stage, the inactivated vaccine developed by Sinopharm group has now entered the phase III clinical trial stage, and has the capacity for mass production, and all progress is leading the world status.

According to Yang Xiaoming, on February 1, when the COVID-19 was raging, China Biotechnology Co., Ltd, as the lead unit, won the key special item of "2019-nCoV inactivated vaccine" of the Ministry of Science and Technology National Key Research and Development Program "Public Security Risk Prevention and Control and Emergency Technology and Equipment" After the urgent establishment of the project, the scientific research team worked overtime to promote vaccine research and development through the "wartime mechanism" of high-intensity work of more than 16 hours a day, and an average breakthrough was made every week.

Due to the sufficient data of pre-clinical research and the severe global epidemic prevention and control situation, the State Food and Drug Administration has opened a "green channel" for

China's Biotechnology COVID-19 inactivated vaccine, and approved phase I/II clinical trials at one time.

On April 12th, the COVID-19 inactivated vaccine developed by the Wuhan Institute of Biological Products of China Biotechnology became the world's first vaccine to enter Phase I/II clinical trials. On April 27th, the COVID-19 inactivated vaccine developed by the Beijing Institute of Biological Products of China Biotechnology also entered phase I/II clinical trials. A total of 2240 people were enrolled in the Phase I/II clinical studies of the two vaccines.



On June 16, the results of phase I / II clinical trial of Wuhan Institute of Biological Products of China Biology showed that the vaccine was safe after vaccination, and there was no serious adverse reaction. After different procedures and doses of vaccination, the vaccinators in the vaccine group produced high titer antibody. The positive conversion rate of neutralizing antibody reached 100% after inoculating two doses on 0 and 28 days.

The results of phase I / II clinical trial conducted by Beijing Institute of Biological Products of China Biology were opened on June 28. The positive conversion rate of neutralizing antibody reached 100% after two doses of vaccination in 0 and 21 days, and 100% in 0 and 28 days.

The novel COVID-19 pneumonia vaccine development team of China has been actively promoting phase III clinical research work, and has undertaken overseas cooperation and signed a framework agreement with the relevant agencies of the severe COVID-19 pneumonia epidemic countries. On June 23, the launching ceremony of international clinical (phase III) of Sinopharm

China Biological COVID-19 inactivated vaccine was held in Beijing, Wuhan and Abu Dhabi of UAE in the form of video conference. The health minister of UAE issued the clinical trial approval document to Sinopharm China biology. China and Abu Dhabi signed relevant clinical cooperation agreements on the spot, which also marks the official launch of the world's first international clinical trial (phase III) of inactivated COVID-19 vaccine.

In addition to the safety and effectiveness of the vaccine itself, the production capacity of the vaccine is also the core factor determining whether a vaccine can be popularized on a large scale. While promoting vaccine research and development, Sinopharm China biology is also promoting the construction of high-level biosafety production facilities at wartime speed.

On April 15th, the world's largest production workshop for inactivated vaccine was newly built by Beijing Institute of Biological Products of China Biology for only 60 day. The new vaccine production capacity will reach 120 million annually. On July 1, after more than 100 days, the world's only COVID-19 vaccine research and development laboratory and production workshop complex--Wuhan Institute of biological products of China, was also announced to be completed. The design capacity of the workshop is 100 million doses per year. The rapid completion of the two vaccine "arms factories" has undoubtedly laid a solid foundation for the large-scale production of COVID-19 vaccine and meeting the future national and even global vaccination needs.



According to the Global Times reporter, at present, China's biological production of COVID-19 inactivated vaccine inventory has reached more than 4 million, this number is still rising, once

China's biological COVID-19 inactivated vaccine has completed the third phase of clinical trials and approved for marketing, it can quickly meet the huge vaccination demand in China.

The incidence and degree of adverse reactions of domestic inactivated COVID-19 vaccine were much lower than those of the same kind of vaccine under development.

The COVID-19 vaccine has not yet come into being, and various worries about the vaccine have emerged. On July 3, Michael Ryan, who's emergency director of health programs, said the study showed that 29% of the COVID-19 samples had a D614g mutation. Sumia Swaminatan, who's chief scientist, said laboratory studies have found that the d614g mutation of the new COVID-19 may accelerate the virus's replication, which means it may enhance its transmission. As soon as the news came out, many people were worried that the vaccine would be invalid before it came into the market.

In this regard, Yang Xiaoming said that it is a common phenomenon that part of the genome site mutation occurs in the process of virus transmission. Only when the virus changes greatly at the protein level, the receptor and target of interaction can be changed. According to the current data, the possibility of large protein level mutation of new COVID-19 is extremely low, and the mutation occurring now is not the mutation of key point, so it is not enough to cause vaccine invalidation. "Our inactivated vaccine can cover all the virus strains found so far, including those isolated after the outbreak Beijing." Yang Xiaoming said.

In addition, Yang Xiaoming also said that in the process of vaccine research and development, Chinese biology will carry out cross protection experiments on different strains of virus. In other words, cross protection experiments will be carried out with antisera obtained from vaccinated animals and strains of different genotypes. If both can be neutralized, there will be no impact on vaccine development. If some can be neutralized and others can not, the research team will conduct cross protection experiments according to the research. In order to ensure the effectiveness of vaccines, we should adjust the research and development strategies of some vaccines in time to meet the actual needs.

According to the public concern about the safety and effectiveness of novel COVID-19 pneumonia inactivated vaccine, Yang Xiaoming said that in order to verify the safety and effectiveness of the novel COVID-19 pneumonia inactivated vaccine, and help the COVID-19 pneumonia inactivated vaccine to be listed at an early date, 180 volunteers of the four level enterprise party and government leaders of the national pharmaceutical group were vaccinated with the COVID-19 inactivated vaccine. The pre-test of volunteers showed that the antibody of the subjects had reached the level of resistance to COVID-19. Recently, more than 1000 cadres and employees of sinopharma group voluntarily vaccinated, which also showed that the vaccine was safe and effective, and the incidence and degree of adverse reactions were far lower than those of similar vaccines under research, which undoubtedly gave the R&D team great confidence. The novel COVID-19 pneumonia vaccine is still working cautiously to promote the phase III clinical trial of the vaccine. It is a safe and effective way to verify the vaccine in a larger population. The results of the phase II clinical blindness test show that the vaccine is very effective.

“There is an old legend in China, called the Holy Farmer tastes all kinds of grass. Chinese biological products workers are like The Holy Farmer. Generations of Chinese biological workers have passed down the dedication of testing medicines with their own bodies from generation to generation. For example, Tang Feifan, known as the "father of Chlamydia", planted trachoma virus in his eyes with the spirit of testing drugs and poisons with his body, and became the first Chinese in the world to discover important pathogens. After the trial production of genetically engineered recombinant cervical cancer vaccine, more than ten young people from the whole research group of China biology, regardless of gender, gave themselves an injection first. On the one hand, it is the spirit of dedication to the pharmaceutical industry, on the other hand, it is also our confidence in the vaccine developed. I think it is a combination of dedication and scientific spirit". Yang Xiaoming said.

The development of COVID-19 inactivated vaccine is not in terms of years and months, but in hours.

Generally speaking, it takes 8-10 years for a new vaccine from project establishment, research and development to trial evaluation, administrative approval and marketing.

However, it only took 98 days from project approval to clinical trial approval of the COVID-19 inactivated vaccine for China biology. After respecting the research and development rules and completing at least six months of three phase clinical trials, CBIO is expected to complete the R & D process of a vaccine in about one year, which is a miracle.

When talking about why China's biology has been able to complete the research and development of the COVID-19 vaccine so efficiently, Yang Xiaoming said that this time's vaccine research and development war has vividly demonstrated our country's great advantages in concentrating on major events and the national system.

In the stage of tackling key problems of vaccine, all research and development units, cooperation units, production units, competent departments of science and technology, medical and health supervision departments and other parties are fully cooperating and doing their best to accelerate vaccine research and development by concentrating their efforts and switching from series to parallel. For example, in the link of vaccine effectiveness evaluation, the former way is to test the effectiveness of different kinds of animals one by one. This time, after adopting the parallel mode, we will carry out the effectiveness test on different kinds of animals at the same time.

Another example is that after the vaccine preparation is completed, in the past, the R & D institutions should first verify themselves to be qualified, and then send them to the China food and Drug Control Institute for verification. This time, the research and development institutions send them to the China food and Drug Control Institute for verification at the same time, so as to shorten the inspection cycle.

"The State Food and Drug Administration (SFDA) issued us the approval for phase I / II clinical trial at 7:00 p.m., and at 9:00 p.m., we inoculated the volunteers with the first injection. Before the

vaccine was approved for clinical trials, the local disease control departments mobilized all the volunteers participating in the trial. It can be said that all units actively perform their duties without any conditions, and the work between each link has achieved an efficient and seamless connection. " Yang Xiaoming said.

Besides, the rapid progress in the research and development of COVID-19 vaccine this time also depends on our continuous large-scale scientific research investment for many years, the establishment of a number of mature technology platforms and talent teams, and the whole industry chain of vaccine research and development has made great progress. The process and quality supervision system is also constantly updated, maintaining the world's advanced level. In this COVID-19 vaccine war, China adopts five technical routes to promote vaccine development: inactivated vaccine, recombinant protein vaccine, adenovirus vector vaccine, attenuated influenza virus vector live vaccine and nucleic acid vaccine. China biology alone has been making unremitting efforts to tackle key problems along the four technical routes at the same time, demonstrating their profound scientific research strength.

"If we say that vaccine research and development is driving an airplane and building an airplane at the same time, then the supply chain of parts related to the R&D link should keep up in time. In recent years, vaccine related industrial chain has been gradually completed. Looking back more than 30 years ago, I developed vaccines in Lanzhou Institute of biological products. Almost all the instruments, equipment and reagents used in the laboratory had to be imported from abroad. It took several months for me to move forward quickly. "Yang Xiaoming said.



Yang Xiaoming, chief scientist of "863 Program" vaccine project of Ministry of science and technology, chairman of China Biotechnology Co., Ltd

We're not running against the United States, we're running against the virus.

Under the background that the COVID-19 vaccine has become the "life-saving straw" to end the epidemic situation, a few countries in the world with scientific research strength and economic foundation to develop COVID-19 vaccine are endowed with various "expectations". At present, China and the United States are regarded as the countries most likely to play the role of saving the world due to the fact that a number of vaccines have entered the phase III clinical trials. The competition between China and the United States on the progress of vaccine research and development has naturally become a hot topic of foreign media speculation.

On May 4, the US "business insider" website published an article describing the vaccine R&D project between China and the United States as a national power struggle similar to the "moon race". The article also quoted a global public health expert as saying who could "win the first place" in vaccine research and development. U.S. security officials and top medical and health experts are worried that if China succeeds first, it will put the United States at a very disadvantageous position.

As for the topic of the China-US vaccine dispute, which foreign media are keen to hype, Yang Xiaoming said that China has long solemnly declared to the world that after the research and development of China's COVID-19 vaccine is completed and put into use, it will serve as a global public product and make China's contribution to realizing the accessibility and affordability of vaccines in developing countries. Concerning the research and development of COVID-19 vaccine, China is also taking the route of working hand in hand with countries in need, looking for a key solution to the COVID-19 pneumonia pandemic together.

As a "seed player" in the research and development of new COVID-19 vaccine, China biology itself has a number of internationally certified vaccine products, and has successful cooperation cases with many vaccine projects of international institutions, and has the experience of large-scale export of vaccines to foreign countries. At present, China biology has completed the construction of COVID-19 inactivated vaccine production workshops in Beijing and Wuhan, with an annual production capacity of 200 million doses. Once the vaccine is successfully launched, it will soon be able to provide a large number of safe, effective and high-quality vaccines for the world. It will not be used to catch some new interests in the world when it suffers from the new COVID-19 pneumonia epidemic.

"Therefore, I don't think there is a China-US debate over the rapid development of the COVID-19 vaccine. We are not in a race with the United States, but with the virus." Yang Xiaoming said.

